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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| INSPIRION DELIVERY SCIENCES, LLC,<br><br>Plaintiff,<br><br>v.<br><br>TEVA PHARMACEUTICALS USA, INC., and ACTAVIS LABORATORIES FL, INC.,<br><br>Defendants. | ) | Civil Action No. _____<br><br>*Document Filed Electronically* |

**COMPLAINT FOR PATENT INFRINGEMENT**

Inspirion Delivery Sciences, LLC ("IDS" or "Plaintiff") brings this action for patent infringement against Defendants Teva Pharmaceuticals USA, Inc. ("Teva") and Actavis Laboratories FL, Inc. ("Actavis FL") (collectively, "Defendants").

1. This is an action by IDS against Defendants for infringement of United States Patent No. 7,955,619 ("the '619 patent"). This action arises out of Defendants' filing of Abbreviated New Drug Application ("ANDA") No. 212900 ("Defendants' ANDA") to engage in the commercial manufacture, use, or sale of a generic version of MorphaBond® (morphine

sulfate) Extended Release, 15 mg, 30 mg, 60 mg and 100 mg Tablets described in Defendants' ANDA (the "ANDA Products") prior to the expiration of the '619 patent.

## THE PARTIES

2. IDS is a Delaware limited liability company with its principal place of business at 100 Southgate Parkway, Suite 150, Morristown, NJ 07960. IDS currently shares in the proceeds from the U.S. sales of MorphaBond® Tablets and is the assignee of '619 patent.

3. On information and belief, Defendant Teva is a company incorporated in Delaware with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

4. On information and belief, Teva presently owns ANDA No. 212900 ("Defendants' ANDA").

5. On information and belief, defendant Actavis FL is a corporation organized and existing under the laws of Florida, having its principal place of business at 2945 W. Corporate Lakes Boulevard, Suite B, Weston, Florida 33331.

6. On information and belief, defendant Actavis FL is an indirect, wholly-owned subsidiary of Teva USA.

7. On information and belief, Defendants jointly prepared and submitted Defendants' ANDA, giving rise to this action.

## JURISDICTION AND VENUE

8. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 1 *et seq*. generally and 35 U.S.C. § 271 specifically.

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

10. This Court has personal jurisdiction over Teva because, on information and belief, Teva has continuous and systematic contacts with the State of New Jersey, has its principal place of business in NJ, regularly conducts business in the State of New Jersey, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of New Jersey, and intends to sell its ANDA Product in the State of New Jersey. Teva is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100250184. On information and belief, Teva is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration Nos. 5000583 and 5003436.

11. On further information and belief, Teva regularly and continuously transacts business within the State of New Jersey, including, but not limited to, maintaining its principal place of business in New Jersey at 400 Interpace Pkwy, Parsippany, NJ 07054, employing residents of New Jersey, and selling products that are intended to be further sold in New Jersey.

12. On information and belief, Teva is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug products described in Defendants' ANDA. On information and belief, Teva also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

13. Additionally, this Court has personal jurisdiction over Teva because it previously has been sued in this Judicial District, did not challenge this Court's exercise of personal jurisdiction over it, and availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See, e.g., Celgene Corporation v. Teva Pharm. USA,*

*Inc., et al.,* Civil Action No. 18-14366 (ES)(MAH); *Boehringer Ingelheim Pharma GMBH & Co., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. No. 14-7811 (BRM)(TJB); *Janssen Prods., L.P., et al. v. Teva Pharmaceuticals USA, Inc., et al.,* Civil Action No. 13-7576 (WHW)(CLW).

14. Venue is proper in this District for Teva pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, it has a regular and established place of business in New Jersey at 400 Interpace Parkway, Parsippany, NJ 07054; Teva intends to sell the ANDA Products for distribution to pharmacies in and throughout New Jersey and will induce acts of infringement and contribute to acts of infringement by selling the ANDA Products for distribution to pharmacies in and throughout New Jersey.

15. This Court has personal jurisdiction over Actavis FL because, on information and belief, Actavis FL has continuous and systematic contacts with the State of New Jersey, has a regular and established place of business in New Jersey, regularly conducts business in the State of New Jersey, either directly or through one or more of its corporate parents, wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of New Jersey, and intends to sell the ANDA Products in the State of New Jersey.

16. On information and belief, Actavis FL regularly and continuously transacts business within the state of New Jersey, including business with its indirect parent corporation Teva, including the development, manufacturing, and preparation of regulatory filings for generic drug products to be sold by and in concert with its parent corporation, Teva, in New Jersey. On information and belief, Actavis FL and Teva acted together and in concert in the preparation and filing of Defendants' ANDA.

17. On information and belief, Actavis FL is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, Actavis FL has aided and will aid in the development, manufacturing, and securing of regulatory approval for the drug products described in Defendants' ANDA. On information and belief, Actavis FL also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

18. Additionally, this Court has personal jurisdiction over Actavis FL because it has been sued in this Judicial District, did not challenge this Court's exercise of personal jurisdiction over it, and availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See United Therapeutics et al. v. Actavis Laboratories FL, Inc.*, Civil Action No. 3:16-cv-01816-PGS-LHG; *Sebela International Ltd. et al. v. Actavis Laboratories FL, Inc. et al.*, Case No. 2:17-cv-04789-CCC-MF; *Valeant Pharmaceuticals International, Inc. et al. v. Actavis Laboratories FL, Inc.*, Civil Action No. 2:16-cv-09038-SRC-CLW; and *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, Civil Action No. 2:15-cv-06934 (SRC/CLW).

19. Venue is proper in this District for Actavis FL pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, on information and belief, it has a regular and established place of business in New Jersey at 400 Interpace Parkway, Parsippany, NJ 07054; Actavis FL intends to manufacture and sell the ANDA Products for distribution to pharmacies in and throughout New Jersey and will induce acts of infringement and contribute to acts of infringement by selling the ANDA Products for distribution to pharmacies in and throughout New Jersey.

## THE PATENT-IN-SUIT

20. The ’619 patent, entitled “Abuse Resistant Drugs, Method of Use and Method of Making,” was duly and legally issued on June 7, 2011, naming Manish S. Shah and Ray J. DiFalco as the inventors. A true and correct copy of the ’619 patent is attached hereto as Exhibit A.

21. Plaintiff IDS is the assignee and lawfully owns all right, title, and interest in the ’619 patent, including the right to sue for infringement thereof.

22. The FDA issues a publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

23. New Drug Application (“NDA”) No. 206544 for MorphaBond® Tablets, was approved by the FDA on October 2, 2015. In accordance with 21 U.S.C. § 355(b)(1), the ’619 patent is listed in the Orange Book in connection with approved NDA No. 206544, as a patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale” of the NDA drug product.

24. The ’619 patent is currently not due to expire until August 12, 2028.

## DEFENDANTS’ ANDA NO. 212900

25. On information and belief, Defendants have submitted ANDA No. 212900 to the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of generic MorphaBond® (morphine sulfate) Extended Release, 15 mg, 30 mg, 60 mg and 100 mg Tablets (the “ANDA Products”), and thereby seek FDA approval of Defendants’ ANDA.

26. On information and belief, Defendants’ ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV certification”) that the ’619 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product. On information and belief, Defendants’ purpose in including a Paragraph IV

certification in the ANDA was to seek the ability to engage in the commercial manufacture and sale of the ANDA Products prior to the expiration of the '619 patent.

27. On information and belief, FDA has not yet approved Defendants' ANDA.

28. On information and belief, Defendants were aware of the '619 patent when ANDA No. 212900 was submitted to the FDA, containing the above-described Paragraph IV certification.

29. Teva notified IDS of its Paragraph IV certification to the '619 patent in a letter dated March 7, 2019 ("Teva's Notice Letter"). Attached to Teva's Notice Letter was a thirty-seven-page document entitled "Teva Pharmaceutical USA, Inc.'s Detailed Factual and Legal Basis for Its Paragraph IV Certification that U.S. Patent No. 7,955,619 Is Invalid, Unenforceable and/or Not Infringed by the Morphine Sulfate, 15 mg, 30 mg, 60 mg, 100 mg Tablet Product Described in Teva Pharmaceutical USA, Inc.'s ANDA No. 212900" that allegedly sets forth Teva's statement of factual and legal basis for its Paragraph IV Certification ("Teva's Detailed Statement").

30. IDS has brought this Action within 45 days of receiving Teva's Notice Letter and Teva's Detailed Statement.

31. According to applicable regulations, Teva's Detailed Statement is required to contain the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed, which must include a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 CFR § 314.95(c); *see also* 21 CFR § 314.52.

32. Teva's Detailed Statement included no statement, evidence, or other factual basis for showing that Defendants' ANDA Products did not meet any limitation of any claim of the '619 patent. Further, Teva's Detailed Statement did not raise, allege, or otherwise proffer any basis that Teva will not infringe any claim of the '619 patent, beyond asserting invalidity of the claims.

33. Teva's Detailed Statement asserted that the '619 patent was invalid as obvious over a single reference. Despite making this assertion, Teva failed to, *inter alia*, resolve the level of ordinary skill in the art, appropriately address claim construction, address the differences between the prior art and the claimed invention, and address why those differences would have been obvious to a person of ordinary skill in the art. In addition, Teva failed to show that certain limitations of multiple claims were at all disclosed or taught in the prior art.

34. Teva's Notice Letter included an "Offer of Confidential Access to Application" pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8), but only to Daiichi Sankyo, Ltd. Subsequent to Teva's Offer of Confidential Access to Application, representatives of IDS and Teva negotiated a mutually agreeable Offer of Confidential Access to Application that imposed mutually-agreeable terms, restrictions, and limitations. On April 12, 2019, IDS executed the jointly negotiated Offer of Confidential Access to Application (the "Executed OCA"). Teva provided Defendants' ANDA to IDS, subject to the Executed OCA, on April 15, 2019.

## COUNT I: INFRINGEMENT OF THE '619 PATENT

35. The allegations of paragraphs 1-34 are realleged and incorporated herein by reference.

36. On information and belief, Defendants submitted Defendants' ANDA to FDA, and thereby seek approval of Defendants' ANDA.

37. IDS owns all right, title, and interest in and to the '619 patent.

38. On information and belief, and based on Teva's Detailed Statement and Defendants' ANDA, the ANDA Products meet all limitations of one or more claims of the '619 patent.

39. Teva has not contested that the ANDA Products infringe the claims of the '619 patent.

40. Defendants' submission of Defendants' ANDA with a Paragraph IV certification regarding the '619 patent was an act of infringement of one or more claims of the '619 patent under 35 U.S.C. § 271(e)(2).

41. On information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Products upon approval of Defendants' ANDA.

42. On information and belief, if approved, Defendants will infringe at least claim 1 of the '619 patent under 35 U.S.C. § 271(a) by making, using, selling, offering for sale, and/or importing the ANDA Products in the United States.

43. On information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of Defendants' ANDA to the FDA.

44. Unless enjoined by this Court, upon FDA approval, Defendants will actively induce infringement of the '619 Patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendants' ANDA, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby induce the infringement of one or more claims of the '619 patent by, *inter alia*, patients, physicians, pharmacies, and pharmaceutical distributors. On information and

belief, upon FDA approval, Defendants will intentionally encourage acts of direct infringement with knowledge of the '619 Patent and knowledge that Defendants' acts are encouraging infringement.

45. On information and belief, Defendants know that their ANDA Products are especially made or adapted for use in infringing the '619 patent and that Defendants' ANDA Products are not a staple article of commerce suitable for substantial noninfringing use. On information and belief, Defendants plan and intend to, and will, contribute to the infringement of the '619 patent upon approval of Defendants' ANDA.

46. IDS will be substantially and irreparably harmed by Defendants' infringing activities unless the Court enjoins those activities. IDS will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Defendants' ANDA Products.

47. Defendants' activities render this case an exceptional one, and IDS is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

## REQUEST FOR RELIEF

**WHEREFORE**, Plaintiff respectfully requests the following relief:

(A) A judgment that Defendants have infringed the '619 patent under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the FDA approval of Defendants' ANDA shall be effective no earlier than the expiration date of the '619 patent.

(C) Entry of a permanent injunction enjoining Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendants or on their behalf from commercially manufacturing, using, offering for sale, or selling the ANDA Products within the United States, or importing the ANDA Products into the

United States, until the day after the expiration date of the '619 patent;

(D) A judgment declaring that making, using, selling, offering to sell, or importing Defendants' ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the '619 patent pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(E) A declaration under 28 U.S.C. § 2201 that if Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendants or on their behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the ANDA Products, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(F) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Products, or any product that infringes the '619 patent, or induces or contributes to such conduct, prior to the expiration of the patents;

(G) A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(H) Costs and expenses in this action; and

(I) Such other and further relief as the Court deems just and proper.

Dated: April 19, 2019

Respectfully submitted,

/s/ *Sean R. Kelly*

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**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Under Local Civil Rule 11.2, the undersigned counsel for Inspirion Delivery Sciences, LLC ("IDS") hereby certifies that this matter is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: April 19, 2019

/s/ *Sean R. Kelly*
Sean R. Kelly

**LOCAL CIVIL RULE 201.1 CERTIFICATION**

Under Local Civil Rule 201.1, the undersigned counsel for IDS hereby certifies that IDS seeks declaratory and injunctive relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: April 19, 2019

/s/ *Sean R. Kelly*
Sean R. Kelly